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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,944	02/01/2002	Thomas J. Schall	019934-003210US	8775

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,944	SCHALL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-49,54,55 and 60- 63* is/are pending in the application.

4a) Of the above claim(s) *60-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-49,54,55 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/28/2005 has been entered.

Status of Claims

2. Claims 1-46, 50-53 and 56-59 are cancelled. Claim 63 is added. Claims 47-49, 54-55 and 60-63 are pending. Claims 60-62 are withdraw for being directed to a non-elected invention. Claims 47-49, 54-55 and 63 are under examination. Claims 47 links the invention(s) set forth in claims 60-62, Groups VII-VIII. These inventions will be rejoined should claim 47 be found allowable.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 47-49, 54-55 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 47 recites the limitation "the genome" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Additionally, the claims are rendered indefinite for it is unclear how the intended detection of mutation is achieved. In the instant, the claims require the analysis of a segment of the CMV genome, however, it is unclear what kind of analysis should be encompassed by the recitation "analysis". Is the analysis a genotypic or phenotypic analysis? Is the analysis directed to a specific portion of the genome or the entire genome? Is the recitation "analysis" also further encompassing method steps, such as isolation of the virus from the compound, that are not implicitly recited in the claims? Moreover, is the recitation "analysis" directed at a specific intended use, such as to detect mutation that is associated with antiviral resistance? If so, Applicant is requested to amend the claims to include the purpose of the intended use.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 47-49 and 63 are rejected under 35 U.S.C. 103(a) as being obvious over Erice[1] in view of Ghose[2] and Schall et al.[3]

One of the applied references has a common inventor, Thomas Schall, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it

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[1] Erice, Resistance of Human Cytomegalovirus to Antiviral Drugs. Clinical Microbiology Reviews, April 1999, pages 286-297.
[2] Ghose (U.S. Patent No. 4692411, published 09/1987)
[3] Schall et al. (60/228974, filed 08/30/2000, as evidenced by U.S. PreGrant Publication No. 20020127544)

constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claimed invention is directed to a method of detecting mutations in cytomegalovirus comprising:

(a) collecting CMV by contacting the blood or tissue of the patient with a compound that binds to CMV, and

(b) analyzing a segment of the genome of the collected CMV to detect the presence and/or absence of a mutation in the CMV genome. The claims identify the composition as having a specific core structure, as identified in claim 47, which is later limited to free base or salt of methiothepin or octoclothepin. The claims later specify that contacting comprises withdrawing blood containing CMV from the patient and flowing the blood into or through a collector that comprises the compound, whereby

CMV is captured by the compound of the collector. The claims also require that the composition bind to CMV US28.

Erice provides a summary of methods used in the art to detect mutations in cytomegalovirus. The methods that Erice discusses comprise collecting CMV and analyzing a segment of the CMV genome obtained from the collected CMV to detect the presence and/or the absence of a mutation in the CMV genome.

Erice does not teach the collection of CMV by contacting the blood or a tissue of a patient with a compound that is specified in claim 47. However, Erice does note the need to develop methods to determine susceptibilities directly in clinical specimens or in primary cultures.

The deficiency noted in Erice is compensated by the teaching of Ghose.

Ghose teaches a method of collecting specific biological products, including viruses, from a sample—including blood, using a biochemical filter. The collection method of Ghose includes a filter for trapping large agglutinates that is formed between the desired biological product and its corresponding agonist.

Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Erice and Ghose. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to provide a method to determine susceptibilities directly in clinical specimens or in primary cultures. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Ghose et al.

teaches a method for collecting specific biological products from a sample the use of a biochemical filter.

Neither Erice nor Ghose et al. teaches contacting CMV with a compound that is encompassed by claim 47. However, the deficiency noted of Erice and Ghose is compensated by the teaching of Schall et al.

Schall et al. teaches of compounds that are encompassed by claim 47 as agonists for CMV. In the instant, CMV is the desired biological product. The compositions Schall et al. teaches are free base or salt of methiothepin and octoclothepin. [Example 3 of Schall et al. reference]

Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Schall et al. with Erice and Ghose et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to collect CMV from a sample containing CMV. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Schall et al. provides compositions that can be use to attract CMV from a sample. Thus, absent evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing the claimed invention.

7. Claims 54-55 are rejected under 35 U.S.C. 103(a) as being obvious over Erice in view of Schall et al., as applied to claim 47 and 49 is addressed above, in further view of Ford-Hutchinson et al.[4]

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[4] Ford-Hutchinson et al. Leukotriene B4, Polymorphonuclear Leukocytes and Inflammatory Exudates in the Rat. Prostaglandins, July 1984, Vol. 28, No. 1, pages 13-27.

Claim 54 requires that collecting comprises placing an implant device containing the compound in contact with the blood of the patient, wherein by CMV in the blood is captured by the compound of the implant device, as required by claim 54. Claim 55 further limits claim 54 by requiring the compound to bind to CMV US28.

The requirement set forth in claim 54 is the same as that set forth in claim 49, which is addressed above.

The relevance of Erice and Schall et al. as applied to claims 47 and 49 is addressed above.

Neither Erice nor Schall et al. teach the placement of an implant device that contains the compound in or on the patient such that the implant device is in contact with the blood of the patient, wherein by CMV in the blood is captured by the compound of the implant device, as required by claim 54.

However, as noted above, Erice does note the need to develop methods to determine susceptibilities directly in clinical specimens or in primary cultures.

The deficiency noted in Erice and Schall et al. is compensated by the teaching of Ford-Hutchinson et al.

Ford-Hutchinson et al. teaches a collection method that comprises the placement of an implant device that contains specific compounds in a subject to collect specific corresponding biological product/receptor(s).

Ergo, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Ford-Hutchinson et al. with Erice and Schall et al. One of ordinary skill in the art at the time the invention was made

would have been motivated to do so to facilitate the collection of CMV from a sample containing CMV. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Ford-Hutchinson et al. teaches a the use of implant devices impregnated with specific compounds to collect specific corresponding biological receptors, and Schall et al. teaches specific compounds that can be use to collect CMV. Thus, absent evidence to the contrary, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing the claimed invention.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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E.Le